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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,678	07/12/2005	Bradley S Galer	448-70 PCT US	5133

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EXAMINER	
LEWIS, AMY A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,678	GALER ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/24/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11,17,32-37 and 42-55* is/are pending in the application.

4a) Of the above claim(s) *5,13-15,32-37 and 42-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,11,12,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/26/07,2/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **with traverse** of Group I (claims 1-6, 11, 17, 32-37, and 42-54), and the species:

> In order to comply with the above requirements, Applicant hereby elects without prejudice, with traverse and for search purposes only:
>
> (a) the GABA analog species elected is Gabapentin;
>
> (b) the NMDA antagonist species elected is Dextromethorphan;
>
> (c) in extended release form; and
>
> (d) for the CNS disorder of Anxiety.

, in the reply filed on 11/24/2008 is acknowledged. As applicant acknowledged the Examiner's request for an election for the presence or absence of an additional active agent (see Remarks p. 4, (d)), and elected the above invention for search purposes, the invention will be examined according to NOT containing the additional active agents (such as in claims 13-15), that is the absence of additional active agents.

The traversal is on the ground(s) that there would not be a burden to search the subject matter of all groups and Applicant alleges that the "disclosure presents only a single invention" (See remarks p. 2). This is not found persuasive because, as stated previously in the Requirement for Restriction:

1) the groups lack a special technical feature, thus unity of invention is lacking in the instant claims.

2) The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the

prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, 13-15, 32-37, 42-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

Claims 1-4, 6, 11, 12, 16, and 17 are examined as far as they read upon the elected species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 11, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5767130 (Olney et al.) in view of U.S. Patent No. 6284794 (Olesen et al.).

Olney et al. teach a method and compositions for treating toxic side effects of NMDA antagonists by co-administration of a "safening agent" (see: abstract and col. 1, lines 5-12). The reference teaches that NMDA antagonists reduce excitotoxic brain damage due to stroke, cardiac arrest, asphyxia (see abstract), as well as reducing intracranial pressure (col. 6, lines 54-58). The reference also teaches that NMDA antagonists, as a result of treating excessive Glutamate (Glu) activation may be useful in the treatment of a variety of chronic diseases (see col. 6, lines 58-67):

> In addition to neuronal damage caused by acute insults, excessive activation of Glu receptors may also contribute to more gradual neurodegenerative processes leading to cell death in various chronic neurodegenerative diseases, including Alzheimer's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), AIDS dementia, Parkinson's disease, and Huntington's chorea (Olney 1990). It is considered likely that NMDA antagonists will prove useful in the therapeutic management of such chronic diseases.

Olney et al. also teach that compounds with act as GABA agonists provide protection against NMDA antagonist neurotoxicity (col. 9, lines 5-55). The reference teaches standard modes of dosing and administration, including sustained and delayed release formulations (see col. 17, line 38 – col. 19, line 10). The reference also teaches administration of the 2 drugs as sequential or together in a single carrier (claims 1-7). The reference teaches that dextromethorphan is a non-competitive NMDA antagonist (col. 2, line 51). The reference, while listing several GABA agonists (see col. 9), does not specifically recite gabapentin as a GABA agonist.

Olesen et al. teach methods and compositions for treating tension headache (see abstract). The reference also teaches that gabapentin is a GABA receptor agonist and is useful in the treatment of tension headache (col. 43, line 55- col. 44, line 8). The reference also teaches that dextromethorphan, as an NMDA antagonist, is also effective in treating tension headache (col. 81, Example 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition comprising both gabapentin (a GABA agonist) and dextromethorphan (an NMDA antagonist). One would have been motivated by the desire to gain the positive treatment effects of the NMDA antagonist while ameliorating its toxic side with the "safening agent" GABA agonist, as taught by Olney et al.

Further, one would also have been motivated to combine the two agents in a single composition, having been taught that both are useful in the treatment of tension headache. MPEP § 2144.06 states the following: "It is prima facie obvious to combine two compositions

each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as gabapentin and dextromethorphan which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) is(are) directed to encompass diasteromers and enantiomers thereof, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these diasteriomers and enantiomers meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities, as well as methods of preparing and separating such racemates. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmacentical Co. Ltd.,* 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614